Guidance for Industry

Fees for Human Drug Compounding Outsourcing Facilities Under Sections 503B and 744K of the FD&C Act

DRAFT GUIDANCE

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Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact The Division of User Fee Management and Budget Formulation at 301-796-7900.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

March 2014

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Center for Drug Evaluation and Research
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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

March 2014

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Guidance for Industry[1]
Fees for Human Drug Compounding Outsourcing Facilities Under The Federal Food, Drug and Cosmetic Act

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA or the Agency) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance is intended for entities that compound human drugs and elect to register as outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act), which was added by the Drug Quality and Security Act (DQSA).[2] Once an entity has elected to register as an outsourcing facility, it must pay certain fees to maintain its status as an outsourcing facility.[3]

This guidance describes the types and amounts of fees that outsourcing facilities must pay, the adjustments to fees required by law, how outsourcing facilities may submit payment to FDA, the consequences of outsourcing facilities' failure to pay fees, and how an outsourcing facility may qualify as a small business to obtain a reduction in fees. FDA has issued separate guidances on registration and listing requirements for outsourcing facilities.[4]

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited or otherwise applicable. The use of the word *should* in FDA guidances means that something is suggested or recommended, but not required.

[1] This guidance was prepared by the Office of Management in the Center for Drug Evaluation and Research at the Food and Drug Administration.
[2] Public Law 113-54, Title I.
[3] See section 503B(a)(9) of the FD&C Act.
[4] See FDA draft guidances, available at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm166743.htm, accessed March 31, 2014.

II. BACKGROUND

On November 27, 2013, the President signed the DQSA into law. The DQSA added a new section 503B to the FD&C Act, creating a category of entities called "*outsourcing facilities*."[5] Outsourcing facilities, as defined in section 503B(d)(4) of the FD&C Act, are facilities that meet all of the conditions described in section 503B(a), including registering with FDA as an outsourcing facility and paying an annual establishment fee. If these conditions are satisfied, a drug compounded by or under the direct supervision of a licensed pharmacist in an outsourcing facility is exempt from two sections of the FD&C Act: (1) Section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use) and (2) section 505 (21 U.S.C. 355) (concerning the approval of human drug products under new drug applications (NDAs) or abbreviated new drug applications (ANDAs)). Drugs compounded in outsourcing facilities are not exempt from the requirements of section 501(a)(2)(B) of the FD&C Act (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice for drugs). The fee provisions for outsourcing facilities in the FD&C Act, as enacted by the DQSA, are described in more detail below.

III. FEES

A. Annual Establishment Fee

1. In General

Beginning in fiscal year (FY) 2015, outsourcing facilities that elect to register with FDA must pay an annual establishment fee.[6] Each year, the registration period for outsourcing facilities begins on October 1st and ends on December 31st.[7] The annual establishment fee is paid at the time of registration and is equal to the sum of $15,000, multiplied by the inflation adjustment factor (described in Section III.B.1), plus the small business adjustment factor (described in Section III.B.2).[8] The fee calculation is reflected in the following equation:

> Establishment fee = $15,000 x inflation adjustment factor + small business adjustment factor

FDA will publish a notice in the *Federal Register* announcing the amount of the establishment fee to be collected in a given FY (based on the calculation set forth above) no later than 60 calendar days before the start of that FY.[9]

[5] The DQSA also removes from section 503A of the FD&C Act the provisions on solicitation of prescriptions and advertising that had been held unconstitutional by the U.S. Supreme Court in 2002. *See Thompson v. Western States Med. Ctr.*, 535 U.S. 357 (2002).
[6] See sections 744K(a)(1) and 503B(a)(9) of the FD&C Act.
[7] See section 503B(b)(1)(A) of the FD&C Act and Guidance on Registration for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act, available at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM377051.pdf.
[8] See section 744K(c)(1)(A) of the FD&C Act.
[9] See section 744K(b)(2) of the FD&C Act.

Upon receiving registration information from a facility that elects to register as an outsourcing facility, FDA will send an invoice for the fee (see Section III.E.1 for information on invoicing and instructions for submitting payments). For a given FY, an outsourcing facility will not be considered registered for purposes of section 503B(b) until the annual establishment fee is paid.[10]

2. Entities that Registered Before October 1, 2014

Outsourcing facilities that registered before October 1, 2014, do not have to pay a fee for FY 2014. To maintain their status as outsourcing facilities in FY 2015, however, those entities will have to register during the FY 2015 registration period (October 1 - December 31, 2014) and pay the relevant fees in accordance with the instructions in Section III.E.1 of this guidance. Failure to pay the fee by December 31, 2014, will result in an entity losing its status as an outsourcing facility. FDA will remove the entity from the list of registered outsourcing facilities, and drugs compounded at the facility will no longer qualify for the exemptions under section 503B(a), unless and until the firm re-registers and pays all required fees.[11] Registration and payment of the annual fee must be repeated every FY.[12]

3. Entities that Register Outside of the Annual Registration Period

Entities that elect to register as outsourcing facilities may register outside of the annual registration period (October 1st to December 31st of each year). Registration is encouraged, and can be done at any time during the year. Registration, regardless of when completed, will last until the end of the official registration period for the year of registration (December 31st).[13] For example, if an outsourcing facility registers on May 1, 2014, the registration will expire on December 31, 2014, and the outsourcing facility will need to register for the following FY during the annual registration period of that year (October 1, 2014 – December 31, 2014).

Registration, whether within, or outside of the annual registration period, will incur a full registration fee, including relevant adjustments. Because an entity must complete payment of the registration fee before it will be considered registered for purposes of section 503B(b), drugs compounded in that facility prior to registration and payment of fees will not qualify for the exemptions for products compounded by registered outsourcing facilities under section 503B(a).[14] See Section IV of this guidance for additional discussion on the consequences of an entity's failure to register and pay fees.

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[10] See sections 503B(a)(9) and 744K(g)(3)(A) of the FD&C Act.

[11] See § 744K(g)(3)(A) of the FD&C Act.

[12] See sections 503B(b)(1)(A)(i) and 744K(g)(3)(A) of the FD&C Act.

[13] For example, if an entity registers in August 2015, which is within FY 2015 but after the registration period for that fiscal year, it will have to register again during the FY 2016 registration period, which lasts from October to December of 2015, to be deemed a registered outsourcing facility for FY 2016. In this example, the entity would have to pay a registration fee for FY 2015 when it registers in August 2015, and a registration fee for FY 2016 when it registers between October and December of 2015. For this reason, entities are encouraged to register and pay all related fees as early in the FY as possible.

[14] See section 744K(g)(3)(A) of the FD&C Act (stating that an outsourcing facility "shall not be considered registered until the date that the facility remits the establishment fee"); section 503B(a)(9) of the FD&C Act (stating that a condition of being an outsourcing facility is the payment of relevant fees); section 503B(d)(4) of the FD&C Act (defining *outsourcing facility*, in part, as a facility that has elected to register as an outsourcing facility and

B. Adjustment Factors

1. Inflation Adjustment Factor

The inflation adjustment factor is a statutorily mandated increase of the annual establishment fee. The inflation adjustment factor is equal to the sum of:

- 1; plus
- the average annual percent change in the cost, per full-time equivalent (FTE) position at FDA, of all personnel compensation and benefits paid for those FTE positions for the first three years of the preceding four fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of an average FTE position at FDA for the first three years of the preceding four fiscal years; plus—
- the average annual percent change in the Consumer Price Index for urban consumers for the first three years of the preceding four years of available data multiplied by the proportion of all costs other than personnel compensation and benefit costs to total costs of an average FTE position at FDA for the first three of the preceding four fiscal years.[15]

The inflation adjustment will compound every year.[16] In other words, the inflation adjustment factor determined in one FY will be added to the total inflation-adjusted fee from the preceding FY. FDA will calculate the inflation adjustment factor before each FY, and the adjusted fee will be published in the *Federal Register*.[17]

2. Small Business Adjustment Factor

Certain small businesses (see Section III.D.1) can qualify for a reduction of the annual establishment fee.[18] Entities that qualify as small businesses under section 744K(c)(4) of the FD&C Act are required to pay only one-third of the annual establishment fee, or $5,000 multiplied by the inflation adjustment factor.[19] This is referred to as a *small business reduction*.

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complies with all requirements in 503B, including payment of fees); and section 503B(a) of the FD&C Act (stating that sections 502(f)(1) and 505 of the FD&C Act will not apply to drugs compounded by or under the supervision of a licensed pharmacist in a facility that elects to register as an outsourcing facility and complies with the conditions of 503B).

[15] See section 744K(c)(2)(A) of the FD&C Act. For an overview of how a user fee-related inflation adjustment factor has been implemented in the past, see the Agency's overview of the Prescription Drug User Fee Act (PDUFA) adjustment factor (21 U.S.C. § 379h(c)(1)), available at http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm173546.htm. The inflation adjustment factor for outsourcing facility fees is similar to the PDUFA inflation adjustment factor, except with respect to the provision for review of the percentage change in the Consumer Price Index. PDUFA compares the percentage change in the Consumer Price Index for urban consumers in the Washington-Baltimore region while section 744K of the FD&C Act compares the percentage change in the Consumer Price Index for urban consumers nation-wide. Notwithstanding this difference, the inflation adjustment factor calculated under PDUFA provides insight into the Agency's implementation of similar statutory language as well as past adjustment amounts.

[16] See section 744K(c)(2)(B) of the FD&C Act.

[17] See section 744K(c)(2)(A) of the FD&C Act.

[18] See section 744K(c)(4) of the FD&C Act.

[19] Id.

Entities that do not qualify for a small business reduction will pay a small business adjustment factor, equal to the total amount lost from each outsourcing facility that was granted a small business reduction divided among all outsourcing facilities not granted such a reduction.[20]

FDA will establish the small business adjustment factor every FY based on its best estimate of the number of small businesses that will pay a reduced fee for that year and the positive adjustment to the establishment fee of the remaining entities needed to achieve total fees equaling the amount FDA would have collected if no entity qualified for the small business reduction. The estimate of the number of small businesses and the amount of the small business adjustment factor will be published in the *Federal Register* at least 60 days before the start of each FY.[21]

C. Reinspection Fee

1. In General

Under section 744K of the FD&C Act, beginning in FY 2015, an outsourcing facility will be assessed a reinspection fee each time it is subject to a reinspection.[22] *Reinspection* is defined as:

> one or more inspections conducted under section 704 subsequent to an inspection conducted under such provision which identified noncompliance materially related to an applicable requirement of this Act, specifically to determine whether compliance has been achieved to the Secretary's satisfaction.[23]

The reinspection fee is designed to reimburse FDA when it must visit a particular outsourcing facility more than once because of noncompliance identified during a previous inspection. The reinspection fee assessed will be the reinspection fee for the fiscal year in which the reinspection takes place.[24] Moreover, a reinspection fee will be incurred for each reinspection that occurs until FDA finds that the noncompliant conditions have been adequately addressed.[25]

The reinspection fee will be equal to $15,000 multiplied by the inflation adjustment factor.[26] The inflation-adjusted reinspection fee for each FY will be published in the *Federal Register* not later than 60 calendar days before the start of each FY.[27]

2. Small Business Reinspection Fees

Section 744K of the FD&C Act provides a small business reduction only for the annual establishment fee, not for the reinspection fee.[28] Therefore, an outsourcing facility that is subject

[20] See section 744K(c)(3) of the FD&C Act.
[21] See sections 744K(c)(3) and 744K(b)(2) of the FD&C Act.
[22] See section 744(a)(1)(B).
[23] See section 744J(4) of the FD&C Act.
[24] See section 744K(a)(1)(B).
[25] See section 744K(a)(2).
[26] See section 744K(c)(1)(B) of the FD&C Act.
[27] See section 744K(b)(2) of the FD&C Act.
[28] See sections 744K(c)(1), 744K(c)(3), 744K(c)(4)(A) of the FD&C Act.

to reinspection will be charged the full inflation-adjusted reinspection fee for each reinspection even if the facility qualifies as a small business.

D. How to Qualify for a Small Business Reduction

1. Which Entities Qualify for a Small Business Reduction?

An entity with gross annual sales totaling $1,000,000 or less in the 12 months ending on April 1 of the FY immediately preceding the FY in which the annual establishment fee is assessed may qualify for a small business reduction.[29] *Gross annual sales* is defined as the "total worldwide gross annual sales, in United States dollars, for an outsourcing facility, including the sales of all of the affiliates of the outsourcing facility."[30] *Affiliate* is defined as a "business entity that has a relationship with a second business entity if, directly or indirectly—(A) one business entity controls, or has the power to control, the other business entity; or (B) a third party controls, or has power to control, both of the business entities."[31]

Entities that seek a small business reduction of the annual establishment fee must make a request for such a reduction by April 30th of the year preceding the fiscal year for which the entity is seeking a reduced fee.[32]

2. Content and Format of Request

To qualify for a small business reduction of the annual establishment fee, an entity must submit to FDA a written request for such a reduction, and a certification that the entity meets the requirements for the reduction.[33] The request must be submitted in a format specified by FDA in guidance, and it must be submitted every year that the firm seeks to qualify as a small business.[34]

This guidance specifies that the format for submitting requests for a small business reduction of the annual establishment fee is Form 3908, attached as Appendix 1.[35] The completed form should be submitted via email to CDERCollections@FDA.HHS.gov, with the subject line containing "Outsourcing Facility Small Business Reduction request."

If an outsourcing facility does not have email access, it can mail a request to FDA via the carrier of its choice. For the most updated physical mailing address, visit this website: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/default.htm.

[29] See section 744K(c)(4)(A) of the FD&C Act.
[30] See section 744J(2) of the FD&C Act.
[31] See sections744J(1) and 735(11) of the FD&C Act.
[32] See section 744K(c)(4)(B) of the FD&C Act.
[33] Id.
[34] Id.
[35] Id.

3. Timing of Requests

Pursuant to section 744K(c)(4)(B) of the FD&C Act, an entity seeking a small business reduction must submit to FDA a written request for such a reduction no later than April 30th of the year immediately preceding the FY for which the fee reduction is sought,[36] even if the entity has qualified for the small business reduction for the previous FY. For example, an entity seeking a small business reduction for FY 2015[37] must submit its complete written small business reduction request no later than April 30, 2014.

FDA will accept small business reduction requests until April 30th of each year, and intends to advise the requesting entity of its decision within 60 calendar days of receipt of the request. FDA intends to send a letter to the entity, via email (or regular mail if the request was by regular mail), notifying it of FDA's decision. Entities granted a reduction should maintain a copy of the letter for their records.

E. How and When to Pay

1. Annual Establishment Registration Fees

Once an entity submits its registration information and FDA has reviewed the information and determined that it is complete, the entity will incur the annual establishment fee.[38] FDA will send an invoice to the entity via email, to the email address indicated in the registration file, or via regular mail if email is not an option. The invoice will contain information about the obligations incurred; the amount owed, including the small business reduction if the entity has qualified for that reduction; and instructions for paying the fee. To facilitate timely payment of fees and registration, FDA expects to send invoices no later than three business days after receiving a registration submission. Because entities will not be considered to be registered as outsourcing facilities until payment is received, FDA suggests that entities pay the invoiced amount immediately upon receiving the invoice. If an entity does not pay the full invoiced amount within fifteen calendar days after FDA issues the invoice, FDA will consider the submission of registration information to have been withdrawn and adjust the invoice to reflect that no fee is due.

Entities that intend to submit registrations during the annual registration period that lasts from October 1 to December 31 should submit their registration information no later than December 10 of each year to allow enough time for review of the registration information, invoicing, and payment of fees before the end of the registration period. As discussed in Section IV, an entity that does not pay its annual establishment fee will not be considered registered as an outsourcing facility for that FY. Entities that have submitted registration information but have not completed the payment process by December 31st, the end of the registration period, will be removed from the list of registered outsourcing facilities as of January 1 of that FY, and drugs compounded at

[36] Id.
[37] FY 2015 runs from October 1, 2014, through September 30, 2015.
[38] See section 744K(g)(1) of the FD&C Act ("An outsourcing facility shall remit the establishment fee due under this section in a fiscal year when submitting a registration pursuant to section 503B(b) for such fiscal year.")

the facility will not qualify for the exemptions under section 503B(a),[39] unless and until the firm has re-registered and paid the fee.

2. Reinspection Fees[40]

After FDA conducts a reinspection, it will send an invoice to the entity via email, to the email address indicated in the registration file, or via regular mail if email is not an option. The invoice will contain information about the obligation incurred, the amount owed, and instructions for paying the fee. The invoiced amount should be paid immediately to avoid statutory penalties.[41] (See Section IV). Once an entity has incurred a reinspection fee, the obligation to pay the fee cannot be discharged except through payment of the fee, unless FDA adjusts the invoice to reflect that no fee is due as a result of a reconsideration decision or successful appeal (see section V of this guidance). If FDA does not receive the reinspection fee within 30 calendar days after invoicing, the fee obligation will be treated as a claim of the United States Government, subject to the provisions of subchapter II of chapter 37 of tile 31, United States Code.[42] Interest and fees will accrue until the obligation is satisfied.

IV. EFFECT OF FAILURE TO PAY FEES

An entity that does not pay its adjusted annual establishment fee for a given FY will not be considered registered as an outsourcing facility under section 503B of the FD&C Act for that FY.[43] The facility will be considered registered, for purposes of § 503B(b), when it pays the total adjusted annual establishment fee for that FY.[44]

Outsourcing facilities that registered in FY 2014 and wish to maintain their status as an outsourcing facility in FY 2015 must register during the FY 2015 registration period, which lasts from October 1, 2014, to December 31, 2014. Failure to register and complete payment by December 31, 2014, will result in the loss of status as an outsourcing facility on January 1, 2015.[45]

Entities that submit registrations outside of the annual registration period must pay all relevant fees to be deemed registered; failure to pay fees will result in the facility being deemed not registered for purposes of § 503B(b).[46]

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[39] See sections503B(a)(9) and 744K(g)(3)(A) of the FD&C Act. See Section IV.

[40] The information regarding the manner in which reinspection fees will be collected and the timeline for payment of the fee, which is outlined here, will also be published in the *Federal Register*. See section 744K(g)(2) of the FD&C Act.

[41] See section 744K(g)(3)(B) and 744K(g)(4) of the FD&C Act.

[42] See section 744K(g)(4) of the FD&C Act.

[43] See section 744K(g)(3)(A) of the FD&C Act.

[44] See section 744K(g)(3)(A) of the FD&C Act (stating that an outsourcing facility "shall not be considered registered until the date that the facility remits the establishment fee"); section 503B(a)(9) of the FD&C Act (stating that a condition of being an outsourcing facility is the payment of relevant fees); and section 503B(d)(4) of the FD&C Act (defining *outsourcing facility*, in part, as a facility that has elected to register as an outsourcing facility and complies with all requirements in 503B, including payment of fees).

[45] Id.

[46] See section 744K(g)(3)(A) of the FD&C Act.

Establishment and reinspection fees must be paid in their entirety.[47] A shortfall in any amount will subject the facility to all relevant penalties.

All drugs manufactured, prepared, propagated, compounded, or processed by a facility that has not paid the full amount of the required establishment fee or any applicable reinspection fee, will be deemed misbranded under section 502 of the FD&C Act.[48] Such drugs will continue to be deemed misbranded until the fees owed by that facility have been paid in full. The facility cannot distribute misbranded drugs in interstate commerce.[49] In addition, because one of the conditions of being an outsourcing facility is the payment of fees, drugs compounded in a facility that has failed to maintain its status as an outsourcing facility are also considered to be unapproved new drugs subject to the premarket approval requirements of section 505 of the FD&C Act.[50]

V. REFUNDS AND DISPUTE RESOLUTION

A. Refunds

Section 744K of the FD&C Act makes no provision for the refund of fees associated with registration and reinspection of outsourcing facilities. Therefore, FDA has determined that fees paid pursuant to sections 503B and 744K of the FD&C Act will not be refunded, even if an entity that has registered as an outsourcing facility subsequently withdraws its registration as an outsourcing facility.

B. Dispute Resolution

1. Reconsideration Request

Disputes that arise between an outsourcing facility and FDA about an FDA decision related to the fee provisions of sections 503B and 744K of the FD&C Act will be handled by CDER's Division of User Fee Management and Budget Formulation, pursuant to 21 CFR § 10.75. For example, if an outsourcing facility maintains that FDA denied its small business reduction request in error, it may request a reconsideration of that decision. Similarly, if an outsourcing facility believes that it was assessed a reinspection fee in error, it may request a reconsideration of that decision.

FDA recommends that requests for reconsideration state the outsourcing facility's rationale for its position that the decision was in error and include any additional information that is relevant to the outsourcing facility's argument. A request for reconsideration should be made within 30 days of the issuance of FDA's decision. FDA will issue a reconsideration decision, affirming or denying the outsourcing facility's request and setting forth the basis for the decision. FDA expects to issue a decision on most reconsideration requests within four months of receiving the request.

[47] See section 744(g)(1), 744(g)(3), and 744(g)(4) of the FD&C Act.
[48] See section 744K(g)(3)(B) of the FD&C Act.
[49] See section 301(a) of the FD&C Act.
[50] See section 503B(a)(9) and 503B(d)(4) of the FD&C Act.

All requests for reconsideration should be sent via email to the Director of the Division of User Fee Management and Budget Formulation, at CDERCollections@FDA.HHS.gov, with the subject title "Request for Reconsideration of Agency Decision – Outsourcing Facility Fee Determination."

If an outsourcing facility does not have email access, it can mail a request to FDA via the carrier of its choice. For the most updated physical mailing address, visit this website: http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm382846.htm

2. Appeal Request

If a request is denied upon reconsideration, the outsourcing facility may choose to appeal the denial in accordance with the procedures laid out in 21 CFR § 10.75. Requests for appeal should be made within 30 days of the issuance of FDA's decision at the reconsideration stage. The following information should be included in the appeal request:

- The original Agency decision
- The request for reconsideration
- The decision on the reconsideration request
- Argument in support of the outsourcing facility's belief that the prior conclusions were in error

The appeal request should also contain particular references to information or analyses already submitted to FDA that the applicant believes is relevant to its position. No new information should be presented in the request for an appeal. All requests for appeals should be submitted in writing to the Director of CDER's Office of Management, at CDERCollections@FDA.HHS.gov, with the subject title "Appeal of Agency's Decision at Reconsideration – Outsourcing Facility Fee Determination."

If an outsourcing facility does not have email access, it can mail a request to FDA via the carrier of its choice. For the most updated physical mailing address, visit this website: http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/ucm382846.htm

APPENDIX 1: FORM 3908

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Outsourcing Facilities for Human Drug Compounding Small Business Establishment Fee Reduction Request

Form Approved: OMB No. xxxx-xxxx
Expiration Date: Xxxxxxx xx, 201x
See PRA Statement on page 2.

Section 1. Company Information

a. Company Name

b. Address 1 *(Street Address)*		g. DUNS Number	h. Federal Tax ID Number
c. Address 2 *(Suite, unit building, floor etc.)*		i. Contact Person	
d. City		j. Telephone Number *(Include area code)*	
e. State	f. ZIP Code	k. Email Address	

Section 2. Affiliate Information

List of Outsourcing Facility's Affiliates as defined in §§ 744J(1) and 735(11) of the FD&C Act. *Please include name and address of all domestic and foreign facility affiliates, the name, phone number, and email address for a responsible point of contact for each affiliate. If necessary, use a continuation sheet for additional affiliates.*

Check box only if facility has NO affiliates: ☐

Section 3. Total Gross Annual Sales

Gross Annual Sales *(as defined in § 744J(2) of the FD&C Act) of the entity and its affiliates for the twelve months ending April 1st of the current fiscal year)*

Section 4. Signature

The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate.
Warning: A willfully false statement is a criminal offense, U.S. Code, title 18, section 1001.

Signature	Printed Name	Date Signed *(mm/dd/yyyy)*

Send Completed Form via electronic mail (preferred) to:
CDERCollections@fda.hhs.gov

For physical mail:
Department of Health and Human Services
Food and Drug Administration
10001 New Hampshire Ave, Mail Stop 2163
Silver Spring, MD 20903

For FDA Use Only Date Received: _____ Approved Denied

Privacy Act Notice: This notice is provided pursuant to the Privacy Act of 1974, 5 U.S.C. 552a. The collection of this information is authorized by 21 USC § 353b, 379j-62 and 371. FDA will use the information to assess, collect and process user fee payments, and, facilitate debt collection under the Debt Collection Improvement Act. FDA may disclose information to courts and the Department of Justice in the context of litigation and requests for legal advice; to other Federal agencies in response to subpoenas issued by such agencies; to HHS and FDA employees and contractors to perform user fee services; to the National Archives and Records Administration and General Services Administration for records management inspections; to the Department of Homeland Security and other Federal agencies and contractors in order to respond to system breaches; to banks in order to process payment made by credit card; to Dun and Bradstreet to validate submitter contact information, and to other entities as permitted under the Debt Collection Improvement Act. Furnishing the requested information is mandatory. Failure to supply the information could prevent FDA from processing user fee payments. Additional detail regarding FDA's use of information is available online: *Privacy Act* and *Website Policies*.

PSC Publishing Services (301) 443-6740 EF

Instructions for Filling Out Form FDA 3908: Outsourcing Facilities for Human Drug Compounding – Small Business Establishment Fee Reduction Request

General Instructions

To qualify for a small business fee reduction for a fiscal year, the Outsourcing Facility's Gross Annual Sales must total $1,000,000 or less for the 12 months ending April 1st of the previous fiscal year. An Outsourcing Facility must complete and return the Small Business Establishment Fee Reduction Request form to the FDA for review by April 30th to receive a fee reduction for the next fiscal year.

Section 1: Company Information

1(a) Company Name: Provide the full legal name of the company.

1(b) Address: Provide the street address of the physical location. Do not include P.O. Box.

1(c) Address: Provide additional information such as a suite number or building number, if applicable.

1(d) City: Provide the city in which the company is located.

1(e) State: Provide the two letter state identifier for which the company is located.

1(f) Zip Code: Provide the United States Postal Service zip code where the company is located.

1(g) DUNS Numbers: Dun and Bradstreet (D&B) provides a DUNS Number. It is a unique nine digit identification number for each physical location of your business. Provide the unique nine digit DUNS number issued by Dun and Bradstreet. To establish a DUNS number, click on the link provided: https://iupdate.dnb.com/iUpdate/viewiUpdateHome.htm

1(h) Federal Tax ID Number: A Taxpayer Identification Number (TIN) is an identification number used by the Internal Revenue Service (IRS) in the administration of tax laws. Provide the company's federal tax ID number.

1(i) Contact Person: The contact person should be an officer or employee of the outsourcing facility with authority to speak on behalf of the facility and bind it legally.

1(j) Telephone Number: Provide a telephone number (include area code). The telephone number is the number where the contact is usually available during normal work hours.

1(k) Email Address: Provide an email address of the person identified in field 1(i).

Section 2: Affiliate Information

Affiliate is defined as a "business entity that has a relationship with a second business entity if, directly or indirectly—(A) one business entity controls, or has the power to control, the other business entity; or (B) a third party controls, or has power to control, both of the business entities." If the company has affiliates, provide the name of the affiliate(s), the address, name, phone number, email address and responsible point of contact for each affiliate(s) associated with the company—include all domestic and foreign affiliates.

If the company does not have any affiliates, check the box located in part 2 of this form.

Section 3: Gross Annual Sales

Gross Annual Sales means the total worldwide gross annual sales, in United States dollars, for an outsourcing facility, including the sales of all domestic and foreign affiliates of the outsourcing facility..

Section 4: Signature

Provide a signature of an officer or employee of the outsourcing facility with authority to speak on behalf of the facility and bind it legally. Print the name and provide the date of signature.

How can I contact the FDA if I have questions?

Email address:
CDERCollections@fda.hhs.gov

Telephone number:
1-301-796-7900

For physical mail:
Department of Health and Human Services
Food and Drug Administration
10001 New Hampshire Ave, Mail Stop 2163
Silver Spring, MD 20903